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crofelemer

CRO-PED Indication: Pediatric diarrhea - India, Asia and other developing regions

Glenmark and AsiaPharm will each develop a pediatric formulation of CRO-PED.

Pediatric diarrhea product attributes:

- Safety in children in the US as young as 3 months and appropriate mechanism for population
- Currently the therapeutic options for children are limited
- Powerful global health benefit, potentially saving lives of millions of children

Crofelemer Access Program

In October, 2008, Napo created the Crofelemer Access Program Global, LLC ("CAP Global"), a B-Lab certified entity, the purpose of which was

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A proprietary gastro-intestinal compound in clinical development for four distinct product indications

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CHILDREN

Crofelemer Access Program

In October, 2008, Napo created the Crofelemer Access Program Global, LLC ("CAP Global"), a B-Lab certified entity, the purpose of which was to raise funds and administer Napo's Crofelemer Access Program ("CAP"). The CAP was established to provide crofelemer at cost to pediatric populations in disaster situations and resource-constrained geographies. The CAP is part of the commitment Napo made to the Clinton Global Initiative in September 2008. Napo's commitment is to develop an FDA-approved pediatric formulation of crofelemer (referred to by Napo as "CRO-PED") for distribution to Direct Relief International's medical partner network (See Alliances). CAP Global was formed to allow socially-conscious investors to support the acceleration of development of CRO-PED. Napo received a cornerstone investment in this program from the principal of Asset Management, a well-known venture fund in Palo Alto, California. The return on investment to those who invested in CAP Global is based on a percent of any royalties on western market sales received by Napo.

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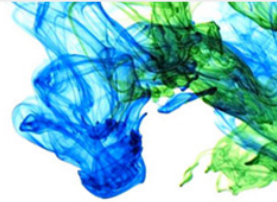
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Crofelemer Mechanism of Action

Crofelemer has a well-documented, novel anti-secretory mechanism of action which reduces excess chloride ion secretion via the CFTR channel. At a functional level, diarrhea is often associated with increased intestinal secretion. The chloride channel CFTR regulates water balance in the intestines through control of chloride ion secretion and sodium absorption. Increased chloride ion secretion, which causes excess fluid in the intestines, can be caused by bacterial toxins, serotonin, inflammatory mediators, and several drugs.

In vitro and in vivo studies of crofelemer have shown that crofelemer inhibits chloride ion secretion and reduces gastrointestinal fluid accumulation by blocking chloride ion efflux through the CFTR channel. Crofelemer does not affect gut motility and is not absorbed systemically to any significant level, two important characteristics associated with the product's demonstrated safety profile and suitability for chronic administration.



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Based on its mechanism of action, i.e. blocking chloride ion secretion through CFTR, CRO-ID was investigated as an agent for the treatment of secretory diarrhea. Since crofelemer specifically blocks the mechanism by which many bacterial toxins produce diarrhea, it is ideally suited to treat the secretory diarrhea produced by acute bacterial infections (traveler's diarrhea and cholera infection). Crofelemer also targets the primary cause of secretory diarrhea associated with some drugs, specifically those used to treat HIV/AIDS. HIV protease inhibitors produce secretory diarrhea by increasing chloride ion secretion in intestinal cells.

This mechanism of action and safety profile provide a strong rationale for treatment of diarrhea in children, for whom there are currently only limited therapeutic options.



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Diagram of secretion of fluid in human intestinal cells

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BUSINESS STRATEGY

The Long Journey from the Amazon to the FDA

Podcast: [March 5, 2012](#)

The Burrill Report

The Burrill Report (March 5, 2012): The Long Journey from the Amazon to the FDA (.MP3, 12.46 Mb)



At the end of February, the U.S. Food and Drug Administration notified Napo Pharmaceuticals that it would grant it a priority review for the company’s application to market its experimental drug Crefelomar to treat chronic diarrhea in people living with HIV or AIDS on antiretroviral therapy. Though legal battles continue for the company over its agreement with partners on the drug, the FDA’s acceptance of its application marks a milestone for a drug and a company that have traveled a long and winding trail to get to this point. We spoke to Lisa Conte, CEO of Napo, about the drug that is derived from a tree that’s plentiful in the Amazon, the company’s unusual development model, and the potential for the drug beyond its initial indication.

March 01, 2012
http://www.burrillreport.com/article-the_long_journey_from_the_amazon_to_the_fda.html

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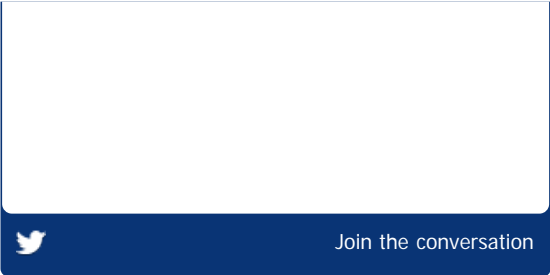
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